

## **REMARKS**

Claims 1-3, 5-10, 13 and 17 are now pending in the application, with claims 1 and 17 being independent claims. No amendments have been made, and thus, no new matter is presented. In view of the following remarks, Applicants respectfully request withdrawal of the rejections.

### **REJECTIONS UNDER 35 U.S.C. § 103**

Claims 1-3, 6-10, 13 and 17 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. 5,593,410 to Vrespa et al. in view of U.S. 6,129,730 to Bono et al. and U.S. 7,811,312 to Stevens. Claim 5 is rejected as obvious over Vrespa, Bono, Stevens and in further view of U.S. 5,180,382 to Frigg et al. Applicants respectfully disagree with the rejections.

Applicants submit that independent claims 1 and 17 are not obvious over the combination of cited references, as the combination of cited references fails to teach every limitation of the claims. In particular, the combination of cited references do not teach “wherein the single-start thread on the tail portion is a continuation of one of the threads of the double-start thread on the lead portion” and “wherein the ratio of the thread aspect ratio of the thread on the tail portion to the thread aspect ratio of the thread on the lead portion is at least about 1.2,” as recited in claims 1 and 17. Nor would it be obvious to modify the primary reference, Vrespa, to include these features.

#### **A. “Wherein the Single-Start Thread on the Tail Portion is a Continuation of One of the Threads of the Double-Start Thread on the Lead Portion”**

Applicants submit that the cited references do not disclose “wherein the single-start thread on the tail portion is a continuation of one of the threads of the double-start thread on the

lead portion,” as recited in independent claims 1 and 17. Out of the cited art, *only* Vrespa illustrates a screw having different threaded portions, and Vrespa certainly does not disclose the *structural* feature of a single start thread on a tail portion being a continuation of one of the threads of a double-start thread of a lead portion.

While the Office Action asserts that Stevens “shows that discontinuous and continuous threading are equivalent structures known in the art,” and cites to Col. 7, lines 65 – Col. 8, line 13 of the reference, such that it would be obvious to modify Vrespa to have continuous threads in view of Stevens, Applicants respectfully disagree. Stevens does not illustrate any of its screws as having different threading, and simply states that instead of a unitary continuous helical thread, “multiple lead helical threads, discontinuous helical threads, variable pitch helical threads, variable outside diameter helical threads, thread-forming self-tapping, thread-cutting self-tapping, and variable root diameter helical threads can be interchanged and combined.” Col. 8, lines 1-5. None of this language even addresses providing a screw with two different threaded portions having distinct single and double threading (e.g., separated by an intermediate transition portion) whereby the “single-start thread on the tail portion is a continuation of one of the threads of the double-start thread on the lead portion.” Stevens simply generalizes that different threads can be combined, and does not recognize having the structural feature of one thread of a single-start thread as a *continuation* of a thread of a double-start thread. Accordingly, one skilled in the art would have no reason to modify Vrespa (which clearly shows a discontinuity in its threads) to include continuous threading between a single-start thread and a double-start thread.

Thus, the cited art does not disclose “wherein the single-start thread on the tail portion is a continuation of one of the threads of the double-start thread on the lead portion,” as recited in

independent claims 1 and 17. And nor would it be obvious to modify Vrespa in view of Stevens to include this feature.

**B. “Wherein the Ratio of the Thread Aspect Ratio of the Thread on the Tail Portion to the Thread Aspect Ratio of the Thread on the Lead Portion is at Least About 1.2”**

Applicants submit that the cited references do not disclose “wherein the ratio of the thread aspect ratio of the thread on the tail portion to the thread aspect ratio of the thread on the lead portion is at least about 1.2.” While Applicants have recognized a distinct benefit to obtaining a higher thread aspect ratio and state that “[i]t has been found that a higher thread aspect ratio for the thread on the tail portion can help to make a secure screw fixation to cancellous bone,” none of the cited art even recognize the benefits of this feature.

While the Office Action states that the claimed ratio would be obvious “since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art,” Applicants respectfully disagree. As noted in Applicants’ prior response, there is no recognition in any of the cited art of the benefits of providing a particular thread aspect ratio. Nor does the Office Action state how one would even go about discovering the “optimum value” of a thread aspect ratio since the cited art does not even recognize the benefits of having a particular thread aspect ratio. See M.P.E.P. 2144.05, section II.B, entitled “Only Result-Effective Variables Can Be Optimized” (“A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable . . .”) (emphasis added).

Applicants respectfully disagree with “the position [in the Office Action] that the value of 1.2 is an optimal value/workable range and [that] it would have been obvious to find the optimal value/workable range and it would have been obvious to find the optimal value/range of the

screw of Vrespa et al. as the device of Vrespa includes two threaded sections (22 and 24, figure 1) which are used to be inserted into bone.” Office Action at p. 8. Applicants submit that while Vrespa does illustrate two different threaded portions, there is absolutely no way to determine what the thread aspect ratio of the thread on the tail portion to the thread aspect ratio of the thread on the lead portion would be, and thus, such a ratio *cannot* be optimized. The thread aspect ratio depends on variables such as the overall diameter and root diameter of the different threaded portions, and Vrespa does not even provide such values in its disclosure. Without such values, one *cannot* even optimize the thread aspect ratio. Nor would it be reasonable to rely simply on Vrespa’s figures to achieve a specific thread aspect ratio, as “[w]hen the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on the measurement of the drawing features are of little value.” M.P.E.P. § 2125. Accordingly, as one skilled in the art would have had no means of even determining an optimal value for the ratio of the thread aspect ratio of the thread on the tail portion to the thread aspect ratio of the thread on the lead portion,” it would not have been obvious to modify Vrespa to have a particular ratio.

Thus, the cited art does not disclose “wherein the ratio of the thread aspect ratio of the thread on the tail portion to the thread aspect ratio of the thread on the lead portion is at least about 1.2,” as recited in independent claims 1 and 17. And nor would it be obvious to modify Vrespa to include this feature.

As Claims 2, 3, 5-10 and 13 depend from Claim 1, Applicants respectfully request the Examiner to reconsider and withdraw the rejections of Claims 2, 3, 5-10 and 13.

### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

### **CONCLUSION**

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned attorney at (610) 930-1800 x1172. No additional fees are believed due for this submission, however, if any additional fees are required; please charge such fees to Globus Medical Deposit Account No. 50-4131.

Respectfully submitted,

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